Roethig, Hans

From: Kinser, Robin D.
Sent: Friday, November 08, 2002 2:16 PM
To: Roethig, Hans
Cc: Kinser, Robin D.
Subject: RE: getting organized

Dear Hans--

Here are my responsibilities as I see them:

- Oversight of development and validation of analytical methodology for biomarker determinations
- Leadership of biomarker selection activity
- Documentation/presentations of research plans and results
- Development of validation guidance (based on appropriate regulatory input) for Clinical Evaluation studies
- Internal resource for Clinical Evaluation directorate on cigarettes, smoking, smoke analysis, analytical chemistry, and physical chemistry
- Contributor to research planning and protocol writing for Clinical Evaluation studies

I look forward to a discussion at our earliest mutual convenience.

--Robin

-----Original Message-----
From: Roethig, Hans
Sent: Tuesday, November 05, 2002 3:43 PM
To: Adams, Candace R.; Feng, Shixia; Gogova, Maria; Jin, Yan; King, Valerie A.; Kinser, Robin D.; Liang, Qiwei; Mawyer, Denise T.; Mendes, Paul; Nelson, Bettie L; Oey, Jan; Roethig, Hans; Sarkar, Mohamadi; Unverdorben, Martin
Subject: getting organized

As we are growing we need more rules to be communicated (it does not mean that we did not have them before, but they were used more unconsciously):
Clinical program leaders will set up study teams for all studies running and being planned. They have to assure that all protocols are seen and agreed to by the study team members including the experts from bio-analytics, statistics/DM and smoking behavior, and others as deemed necessary.
The final step for new protocols is a WSA review. Who these reviewers will be has to be decided case by case, normally Rick's staff.
I also like you to put together a list of projects and activities you think you are responsible for. Please send this to me before November 8, so we can discuss it. Please bring the list to the next staff meeting for a first discussion.
Best regards
Hans

ACCORD or SCoR